IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

CELGENE CORPORATION, **Plaintiff,** **v.** **MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN N.V.,** **Defendants.**	**Civil Action No. 20-00003 (IMK)** **AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **FILED UNDER SEAL** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Amended Complaint against defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "Mylan"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from Mylan's filing of Abbreviated New Drug Application ("ANDA") No. 213912 ("Mylan's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's REVLIMID® drug products prior to the expiration of United States Patent Nos. 7,189,740 ("the '740 patent"), 7,465,800 ("the '800 patent"), 7,855,217 ("the '217 patent"), 7,968,569 ("the '569 patent"), 8,404,717 ("the '717 patent"), 8,530,498 ("the '498 patent"), 8,648,095 ("the '095 patent"), 9,056,120 ("the '120 patent"), 9,101,621 ("the '621 patent"), and 9,101,622 ("the '622 patent") (collectively, "the patents-in-suit"), owned by Celgene.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and

development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Defendant Mylan N.V. is a corporation organized and existing under the laws of Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL109UL, England. On information and belief, the Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania.

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, Pennsylvania 15317.

6. On information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

7. On information and belief, Mylan Inc. is a wholly owned subsidiary of Mylan N.V.

8. On information and belief, Mylan N.V. and Mylan, Inc., participated in operations related to preparing ANDA No. 213912 and/or contributed employees to the preparation of ANDA No. 213912.

The Patents-in-Suit

9. On March 13, 2007, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '740 patent, entitled "Methods of Using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes," to Celgene as assignee. A copy of the '740 patent is attached hereto as Exhibit A.

10. On December 16, 2008, the USPTO duly and lawfully issued the '800 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '800 patent is attached hereto as Exhibit B.

11. On December 21, 2010, the USPTO duly and lawfully issued the '217 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '217 patent is attached hereto as Exhibit C.

12. On June 28, 2011, the USPTO duly and lawfully issued the '569 patent, entitled "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '569 patent is attached hereto as Exhibit D.

13. On March 26, 2013, the USPTO duly and lawfully issued the '717 patent, entitled "Methods of Treating Myelodysplastic Syndromes Using Lenalidomide," to Celgene as assignee. A copy of the '717 patent is attached hereto as Exhibit E.

14. On September 10, 2013, the USPTO duly and lawfully issued the '498 patent, entitled "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione," to Celgene as assignee. A copy of the '498 patent is attached hereto as Exhibit F.

15. On February 11, 2014, the USPTO duly and lawfully issued the '095 patent, entitled "Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione In Combination With Proteasome Inhibitor," to Celgene as assignee. A copy of the '095 patent is attached hereto as Exhibit G.

16. On June 16, 2015, the USPTO duly and lawfully issued the '120 patent, entitled "Methods of Treating Myelodysplastic Syndromes with a Combination Therapy Using Lenalidomide and Azacitidine," to Celgene as assignee. A copy of the '120 patent is attached hereto as Exhibit H.

17. On August 11, 2015, the USPTO duly and lawfully issued the '621 patent, entitled "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione After Stem Cell Transplantation," to Celgene as assignee. A copy of the '621 patent is attached hereto as Exhibit I.

18. On August 11, 2015, the USPTO duly and lawfully issued the '622 patent, entitled "Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone," to Celgene as assignee. A copy of the '622 patent is attached hereto as Exhibit J.

The Revlimid® Drug Product

19. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 021880), which it sells under the trade name REVLIMID®.

20. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

21. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to REVLIMID®.

22. The labeling for REVLIMID® instructs and encourages physicians, pharmacists, and other healthcare workers and patients to administer REVLIMID® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

23. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

24. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia. On information and belief, Mylan Pharmaceuticals Inc. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in West Virginia, this Court has personal jurisdiction over Mylan Pharmaceuticals Inc.

25. On information and belief, Mylan Pharmaceuticals Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Mylan's ANDA. On information and belief, Mylan Pharmaceuticals Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

26. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia. On information and belief,

Mylan Inc. purposefully has conducted and continues to conduct business in this Judicial District.

27. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Mylan's ANDA. On information and belief, Mylan Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

28. This Court has personal jurisdiction over Mylan N.V. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in West Virginia, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Mylan Pharmaceuticals Inc. and Mylan Inc., companies registered with the West Virginia Secretary of State, and (2) maintains extensive and systematic contacts with the State of West Virginia, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in West Virginia including through, directly or indirectly, Mylan Pharmaceuticals Inc. and Mylan Inc.

29. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Inc. because, *inter alia*, they: (1) have purposefully availed themselves of the privilege of doing business in West Virginia, including directly or indirectly through their subsidiaries, agents, and/or alter egos, including companies registered with the West Virginia Secretary of State; and (2) maintain extensive and systematic contacts with the State of West Virginia, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in West Virginia including through, directly or indirectly, their subsidiaries, agents, and/or alter egos.

30. This Court has personal jurisdiction over Mylan because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Mylan intends a future course of conduct that includes acts of patent infringement in West Virginia. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in West Virginia and in this Judicial District.

31. Mylan N.V.'s website (http://www.mylan.com/en/company/corporate-governance) states that "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

32. Mylan N.V.'s Form 10-K Annual Report for the Period Ending 12/31/2016 ("Mylan 2016 Annual Report") states that on February 27, 2015, "Mylan Inc. became an indirect wholly owned subsidiary of Mylan N.V., and Mylan Inc.'s common stock ceased trading on the NASDAQ." (*See* Mylan 2016 Annual Report at 53, available at https://investor.mylan.com/node/20216/html.) The Mylan 2016 Annual Report further states that "Mylan N.V. is the successor to Mylan Inc." (*Id.* at 55.)

33. Mylan N.V.'s Form 10-K Annual Report for the Period Ending 12/31/2017 ("Mylan 2017 Annual Report") describes the company as "One Mylan," with a "horizontally and vertically integrated platform with global scale." (*See* Mylan 2017 Annual Report at 3, available at https://investor.mylan.com/node/27026/html.) On information and belief, Mylan has often referred to itself as "One Mylan."

34. Mylan's CEO has stated that Mylan "operating under one brand will allow us to speak with a more unified and powerful voice." (*See* http://newsroom.mylan.com/press-releases?item=122962)

35. In petitions for *Inter Partes* Review ("IPR") before the Patent Trial and Appeal Board of the United States Patent and Trademark Office, Mylan Pharmaceuticals Inc. has described Mylan Inc. and Mylan N.V. as the "real parties in interest" pursuant to 37 C.F.R. § 42.8(b)(1). (*See, e.g.,* IPR2020-00040, Petition for *Inter Partes* Review at 6.) The Federal Circuit has defined a "real party in interest" as "a clear beneficiary" of invalidating the patent that "has a preexisting, established relationship with the petitioner." *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018).

36. On information and belief, Mylan uses one website in the United States—www.mylan.com—with one hiring webpage. (*See* https://mylan.taleo.net/careersection/myl_usajobs/jobsearch.ftl)

37. On information and belief, Mylan uses one newsroom for press releases involving products from various subsidiaries. (*See* http://newsroom.mylan.com/press-releases)

38. On information and belief, Mylan N.V. shares its corporate officers and directors with its subsidiaries, including Mylan Inc. and MPI.

39. On information and belief, Mylan N.V.'s CEO and executive officers operate out of the same location as Mylan Inc. (*See* https://www.mylan.com/en/contact-mylan.)

40. On information and belief, Mylan Pharmaceuticals, Inc. "holds nearly 80% of Mylan N.V.'s ANDAs and NDAs listed in the Orange Book," and acts at the direction and for the benefit of its parent companies and is controlled and/or dominated by its parent companies. *See Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, No. 17–379, 2017 WL 3980155, at *18 (D. Del. Sept. 11, 2017).

41. On information and belief, Mylan N.V. uses its subsidiaries in the United States as vehicles to prepare and file its ANDAs, including ANDA No. 213912. (*See https://www.regulations.gov/document?D=FDA-2017-N-3615-0044* at 200:5-17.)

42. On information and belief, Mylan N.V. is a holding company with no employees. (*See* Letter from Bradley L. Wideman, Vice President, Associate General Counsel, Mylan Inc. to Securities and Exchange Commission dated February 12, 2015 at 1 (https://www.sec.gov/divisions/corpfin/cf-noaction/2015/mylan-021815-12g3-incoming.pdf).)

43. On information and belief, Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District, including with respect to Mylan's ANDA.

44. On information and belief, Mylan Pharmaceuticals Inc. acts at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and is controlled and/or dominated by Mylan N.V. and Mylan Inc.

45. On information and belief, Mylan Pharmaceuticals Inc. did not act alone in the submission of Mylan's ANDA, such that each defendant submitted Mylan's ANDA.

46. On information and belief, each of Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. intend to benefit and will benefit from the approval of Mylan's ANDA should Mylan's ANDA receive FDA approval.

47. On information and belief, Mylan N.V. is a publicly traded company.

48. On information and belief, Mylan N.V. and its subsidiaries operate as a singular, "global pharmaceutical company" that offers a portfolio "of more than 7,500 products," and that Mylan makes public representations regarding the same. (*See, e.g.*, Mylan N.V. February 27,

2020 10-K, available at https://investor.mylan.com/node/28936/html.) On information and belief, members of the Mylan corporate family have locations in or are incorporated in the State of West Virginia. On information and belief, these entities are controlled and/or dominated by Mylan Pharmaceuticals Inc., Mylan Inc., and/or Mylan N.V. and/or are alter egos of Mylan Pharmaceuticals Inc., Mylan Inc., and/or Mylan N.V.

49. On information and belief, Mylan's ANDA contains references to "Mylan Inc."

50. On information and belief, Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V., directly or indirectly or through each other or other entities, maintain regular and established places of business in West Virginia.

51. On information and belief, Mylan Pharmaceuticals Inc. has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Keryx Biopharmaceuticals, Inc., et al. v. Mylan Pharm. Inc.*, No. 19-00040 (N.D.W. Va.).

52. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

Acts Giving Rise To This Suit

53. Pursuant to Section 505 of the FFDCA, Mylan filed Mylan's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of lenalidomide capsules 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg ("Mylan's Proposed Products"), before the patents-in-suit expire.

54. On information and belief, following FDA approval of Mylan's ANDA, Defendants Mylan Pharmaceuticals Inc., Mylan N.V. ,and Mylan Inc. will work in concert with one another to make, use, offer for sale, or sell Mylan's Proposed Products throughout the United States, or import such generic products into the United States.

55. On information and belief, in connection with the filing of its ANDA as described above, Mylan provided a written certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Mylan's Paragraph IV Certification"), alleging that the claims of the '740 patent, the '800 patent, the '217 patent, the '569 patent, the '717 patent, the '498 patent, the '095 patent, the '120 patent, and the '622 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Mylan's ANDA.

56. On information and belief, a Mylan Inc. employee reviewed and signed Mylan's Paragraph IV Certification and has reviewed and signed subsequent FDA correspondence concerning Mylan's ANDA.

57. No earlier than November 20, 2019, Mylan sent written notice of its Paragraph IV Certification to Celgene ("Mylan's Notice Letter"). Mylan's Notice Letter alleged that the claims of the '740 patent, the '800 patent, the '217 patent, the '569 patent, the '717 patent, the '498 patent, the '095 patent, the '120 patent, and the '622 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Mylan's ANDA. Mylan's Notice Letter also informed Celgene that Mylan seeks approval to market Mylan's Proposed Products before the patents-in-suit expire.

Count I: Infringement of the '740 Patent

58. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

59. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '740 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

60. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '740 patent.

61. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '740 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

62. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '740 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that its acts are encouraging infringement.

63. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '740 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '740 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

64. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '740 patent is not enjoined.

65. Celgene does not have an adequate remedy at law.

66. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '800 Patent

67. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

68. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

69. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '800 patent.

70. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

71. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

72. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of

the ’800 patent and that there is no substantial non-infringing use for Mylan’s Proposed Products.

73. Celgene will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’800 patent is not enjoined.

74. Celgene does not have an adequate remedy at law.

75. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count III: Infringement of the ’217 Patent

76. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

77. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Products, prior to the expiration of the ’217 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

78. There is a justiciable controversy between Celgene and Mylan as to the infringement of the ’217 patent.

79. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’217 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States.

80. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will induce infringement of one or more claims of the ’217 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States. On information and belief, upon FDA approval of Mylan’s ANDA, Mylan will

intentionally encourage acts of direct infringement with knowledge of the '217 patent and knowledge that its acts are encouraging infringement.

81. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '217 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '217 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

82. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '217 patent is not enjoined.

83. Celgene does not have an adequate remedy at law.

84. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '569 Patent

85. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

86. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '569 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

87. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '569 patent.

88. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '569 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

89. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '569 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that its acts are encouraging infringement.

90. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '569 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '569 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

91. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '569 patent is not enjoined.

92. Celgene does not have an adequate remedy at law.

93. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '717 Patent

94. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

95. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '717 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

96. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '717 patent.

97. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '717 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

98. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '717 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '717 patent and knowledge that its acts are encouraging infringement.

99. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '717 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of

the ’717 patent and that there is no substantial non-infringing use for Mylan’s Proposed Products.

100. Celgene will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’717 patent is not enjoined.

101. Celgene does not have an adequate remedy at law.

102. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count VI: Infringement of the ’498 Patent

103. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

104. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Products, prior to the expiration of the ’498 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

105. There is a justiciable controversy between Celgene and Mylan as to the infringement of the ’498 patent.

106. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’498 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States.

107. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will induce infringement of one or more claims of the ’498 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States. On information and belief, upon FDA approval of Mylan’s ANDA, Mylan will

intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that its acts are encouraging infringement.

108. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '498 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '498 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

109. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '498 patent is not enjoined.

110. Celgene does not have an adequate remedy at law.

111. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '095 Patent

112. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

113. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '095 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

114. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '095 patent.

115. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '095 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

116. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '095 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that its acts are encouraging infringement.

117. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '095 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '095 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

118. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '095 patent is not enjoined.

119. Celgene does not have an adequate remedy at law.

120. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '120 Patent

121. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

122. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '120 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

123. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '120 patent.

124. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '120 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

125. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '120 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '120 patent and knowledge that its acts are encouraging infringement.

126. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '120 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of

the ’120 patent and that there is no substantial non-infringing use for Mylan’s Proposed Products.

127. Celgene will be substantially and irreparably damaged and harmed if Mylan’s infringement of the ’120 patent is not enjoined.

128. Celgene does not have an adequate remedy at law.

129. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count IX: Infringement of the ’621 Patent

130. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

131. Mylan’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan’s Proposed Products, prior to the expiration of the ’621 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

132. There is a justiciable controversy between Celgene and Mylan as to the infringement of the ’621 patent.

133. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will infringe one or more claims of the ’621 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States.

134. Unless enjoined by this Court, upon FDA approval of Mylan’s ANDA, Mylan will induce infringement of one or more claims of the ’621 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan’s Proposed Products in the United States. On information and belief, upon FDA approval of Mylan’s ANDA, Mylan will

intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that its acts are encouraging infringement.

135. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '621 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '621 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

136. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '621 patent is not enjoined.

137. Celgene does not have an adequate remedy at law.

138. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '622 Patent

139. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

140. Mylan's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Mylan's Proposed Products, prior to the expiration of the '622 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

141. There is a justiciable controversy between Celgene and Mylan as to the infringement of the '622 patent.

142. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will infringe one or more claims of the '622 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States.

143. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will induce infringement of one or more claims of the '622 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, upon FDA approval of Mylan's ANDA, Mylan will intentionally encourage acts of direct infringement with knowledge of the '622 patent and knowledge that its acts are encouraging infringement.

144. Unless enjoined by this Court, upon FDA approval of Mylan's ANDA, Mylan will contributorily infringe one or more claims of the '622 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Mylan's Proposed Products in the United States. On information and belief, Mylan has had and continues to have knowledge that Mylan's Proposed Products are especially adapted for a use that infringes one or more claims of the '622 patent and that there is no substantial non-infringing use for Mylan's Proposed Products.

145. Celgene will be substantially and irreparably damaged and harmed if Mylan's infringement of the '622 patent is not enjoined.

146. Celgene does not have an adequate remedy at law.

147. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Mylan has infringed the patents-in-suit by submitting ANDA No. 213912;

(B) A Judgment that Mylan has infringed, and that Mylan's making, using, offering to sell, selling, or importing Mylan's Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 213912 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Mylan's Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Mylan's Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Mylan has committed any acts with respect to the solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, other than those acts

expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Mylan engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Mylan's Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: July 20, 2020

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